PATENT
Docket No.: 12013/47901

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	Lixiao WANG, et al.
SERIAL NO.	:	10/694,050
FILED	:	October 28, 2003
FOR	:	METHOD AND APPARATUS FOR SELECTIVE ABLATION OF COATINGS FROM MEDICAL DEVICES
GROUP ART UNIT	:	1725
EXAMINER	:	Samuel M. Heinrich

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION PURSUANT TO 37 C.F.R. § 1.144 FOR WITHDRAWAL OF THE RESTRICTION REQUIREMENT AND REJOINDER OF THE CLAIMS

S I R:

The undersigned submits this petition pursuant to 37 C.F.R. § 1.144 seeking withdrawal of the restriction requirements set forth in the August 16, 2006, Office Action, and reentry of the erroneously withdrawn claims. The withdrawn claims should be examined together with the non-withdrawn claims because they have already been searched and examined together no less than three times, with common references cited across the restriction requirement. Thus, given the fact that these claims have already been searched and examined together, no credible argument exists that searching and examining them again together present a serious burden to the examiner. *See* MPEP § 808 (The Office Action must explain "the reasons why there would be a serious burden on the examiner if restriction is not required."). Indeed, the Examiner has failed to provide any plausible reasoning as to why non-restriction imposes such an undue burden, as

required by the MPEP. Accordingly, withdrawal of the restriction requirements and rejoinder of the restricted claims is respectfully requested.

STATUS OF THE AMENDMENTS

Since filing the pending application with 22 claims over three years ago, the claims have been examined at least three times in Office and Advisory Actions.[1] With each communication from the PTO over the time period between August 30, 2005 and May 23, 2006, the pending claims were examined and considered together, and multiple searches were conducted.

Then, in response to Applicants' filing of an RCE which amended only one claim that narrowed the scope of general subject matter that had been pending for nearly three years, on August 16, 2006 the Examiner for the first time imposed a three-way restriction/election requirement, asserting that, without restriction, a serious burden is imposed on the Examiner because "the inventions require a different field of search." That August 16, 2006, Election/Restriction Office Action identified three claim groupings, as follows:

I. Claims 1-7 and 10-12, laser methods comprising target removal amount.
II. Claims 8 and 23-26, laser treatment of a stent.
III. Claims 13-22, laser apparatus.

See Office Action of Aug. 16, 2006, p. 2.

[1] Prosecution Chronology - This application was originally filed on October 28, 2003 with twenty-two claims. The first Office Action of August 30, 2005, examined and rejected all twenty-two claims. Some of these claims were amended, one was canceled (claim 9), and new dependent claims 23-26 were added in the Applicants' November 11, 2005, response. All pending claims 1-8 and 10-26 were re-examined in the next Office action, mailed February 7, 2006, which was made final. Applicants filed a Response to the Final Office Action on May 2, 2006, which did not propose any claim amendments. All pending claims were again re-examined a third time in the Advisory Action, mailed May 23, 2006. An RCE and amendment, which amended only one claim, were filed on June 7, 2006. An Election/Restriction was mailed August 16, 2006, in response. Applicants filed an Election traversing the restriction requirement and requesting reconsideration and withdrawal of the Election/Restriction on September 28, 2006. On December 5, 2006, the Patent Office acknowledged the traversal, but nevertheless made final the restriction requirement. Applicants herewith file this petition.

The Examiner stated that a restriction was required for two reasons. First, a restriction was required between either the process (groups I & II) or apparatus (III) claims. *Id.*, p. 2 ("Inventions I & II and Invention III are related as process and apparatus for its practice."). To satisfy his burden of explaining "the reasons why there would be a serious burden on the examiner if restriction is not required" (*see* MPEP § 808), the Examiner offered only the conclusory statement that the inventions "require a different field of search (see MPEP § 808.02)." *See* Office Action of Aug. 16, 2006, p. 2.

Second, the Examiner required an election between the species of Group I and Group II. *Id.* The Election/Restriction Office Action stated that the "application contains claims to the following patentably distinct species:

I. Claims 1-7 and 10-12, laser target amount removal on a device.
II. Claims 8 and 23-26, laser treatment of a stent.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species." *Id.* The Office Action continued, stating that there are no generic claims between the two species. *Id.*

In response, the Applicants traversed the restriction/election requirement and requested reconsideration and withdrawal of the Election/Restriction based on several grounds. Applicants also provisionally elected Group III with traverse. The Examiner nevertheless maintained and made final the restriction requirement, stating that "the apparatus can be used for other processes such as making cardboard cartons." *See* Dec. 5, 2006, Office Action, p. 2.

As the Applicants previously traversed and requested reconsideration and withdrawal of the Election/Restriction, which the Examiner made final, Applicants now petition the Director for withdrawal of the erroneous restriction requirements and rejoinder of all claims.

For convenience, the Applicants attach at the end of this petition the claims as presented to the Examiner in Applicants' June 7, 2006, RCE filing, to which the Examiner responded with the Election/Restriction Office Action on August 16, 2006.

ARGUMENT

A. The Restriction Requirement Between Groups I & II and Group III Is Improper

The Examiner has failed to provide any reason why a serious burden is imposed should restriction between the process claims (Groups I & II) and apparatus claims (Group III) not be required. Indeed, there is no such serious burden, as the claims have already been searched and examined together no less than three times, with identical art cited against both the process and apparatus claims.

1. The Examiner Has Not Satisfied His Burden Of Providing The Reasons Why Not Requiring A Restriction Would Impose A Serious Burden.

The August 16, 2006, Election/Restriction Office Action stated that restriction is required because the "Inventions I & II and Invention III are related as process and apparatus for its practice." *See* Office Action of Aug. 16, 2006, p. 2. The MPEP requires that the Office Action explain "the reasons why there would be a serious burden on the examiner if restriction is not required." *See* MPEP § 808. To satisfy his burden, the Examiner offered only the terse statement that the inventions "require a different field of search (see MPEP § 808.02)." *See* Office Action of Aug. 16, 2006, p. 2. Such conclusory statements cannot satisfy the Examiner's burden. *See* MPEP § 803 (a mere statement of conclusion is inadequate); *see also* MPEP § 808.02.

The Examiner later attempted to provide the missing reasons in maintaining the restriction/election requirement, stating that "the apparatus can be used for other processes such as making cardboard cartons." *See* Dec. 5, 2006, Office Action, p. 2. However, the apparatus claimed "identifies the positioning of at least one strut of a medical device" and includes a laser wherein the "laser ablates the selected portion of the coating from the medical device as the medical device is rotated." *See* Application, independent claim 13. Thus, Applicants respectfully assert that the claimed apparatus for laser ablating a coating of a medical device by identifying a strut of the medical device cannot be used to make "cardboard cartons."

Accordingly, Applicants submit that the Examiner has not provided the required reasoning as to why a serious burden exists. *See* MPEP §§ 808, 803.

2. No Serious Burden Exists Because The Claims Have Been Searched And Examined Together No Less Than Three Times.

Applicants respectfully ask for withdrawal of the restriction and rejoinder of the claims because at least the inventions of group I & II, on the one hand, and group III on the other, as identified by the Examiner, are sufficiently related, and examination of these inventions together does not, and did not, create a serious burden on the Examiner. "If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct invention." MPEP §803 (emphasis added).

Here, the subject matter of each of the pending claims has already been searched multiple times. In fact, in the last search conducted in concert with the Final Office Action, the exact same four references were cited in rejecting claims (claims 8 and 13-26) that span across the restriction requirement of groups II and III, covering both apparatus and method claims. Thus, those method and apparatus claims were previously searched and examined together without any serious burden. Where "there is no clear indication of separate future classifications and fields of search, no reasons exist for dividing among inventions." *See* MPEP § 808.02. As demonstrated by the Examiner's citation of identical art across the restriction requirement, the process and apparatus claims could be, and were, searched and examined together. Accordingly, there can be "no clear indication of separate classifications and fields of search," and thus "no reason exists" for restriction. *See* MPEP § 808.02. No prior Office Actions have ever expressed any undue burden as well. Further, since those claims were not amended in the Response filed with the RCE on June 7, 2006, there can be no credible argument that a serious burden now exists between the method and apparatus claims.

The general subject matter of the method claims in Group I has likewise already been examined, considered and searched multiple times. Although the Applicants' June 7, 2006,

Response and RCE amended one independent claim in Group I, the Applicants submit that the subject matter of the amendment entered in that Response must also have been searched during the previous three examinations of the claims. Because the untimely requirement for a restriction follows several office actions on the merits, there is no basis for requiring withdrawal of any claims.

For at least these reasons, a co-extensive search could be carried out without a serious burden, as previous Office Actions have done. As such, Applicants respectfully request withdrawal of the restriction requirement between Group III and Groups I & II, collectively, and rejoinder of the erroneously withdrawn claims.

B. The Election/Restriction Requirement Between Group I and Group II Is Improper

The Examiner has likewise failed to provide any reasons why the alleged species of Groups I and II are distinct, or why a serious burden is imposed should election/restriction not be required. Indeed, the Examiner expressly omitted the key sentence that specifically asked for the required reasoning in his form paragraph response.

The Election/Restriction Office Action stated that the "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species" between Groups I and II. *See* Office Action of Aug. 16, 2006, p. 2. Applicants traversed this restriction/election requirement as the Office action lacked the required explanations to justify its untimely restriction. The MPEP demands that "[e]very requirement to restrict have two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention as claimed is either independent or distinct from the other; and (B) the reasons why there would be a serious burden on the examiner if restriction is not required." *See* MPEP § 808. Here, the Election/Restriction Office Action has neither provided an explanation of (1) why the claims in group I and II are independent or distinct, nor (2) why non-restriction imposes a serious burden. Rather, the only explanation offered is that group I and II are species. This does not satisfy the Examiner's burden. *See* MPEP § 803 (a mere statement of conclusion is inadequate); *see also* MPEP § 808.02.

1. The Examiner Failed To Provide Any Explanation Of Why The Species Are Independent Or Distinct, And Thus Has Not Satisfied His Burden.

First, the Examiner has failed to provide any reasons as to why the claims in group I and II are independent or distinct, as required. *See* MPEP § 808 (restriction requirements must provide "the reasons (as distinguished from the mere statement of conclusion) why each invention as claimed is either independent or distinct from the other"). In requiring the election among species in the Election/Restriction Office Action, the Examiner used form paragraph ¶ 8.01. *Compare* Office Action of Aug. 16, 2006, p. 2; *with* MPEP § 809.02(a), Form ¶ 8.01. However, in doing so, the Examiner omitted the key intervening sentence from Form ¶ 8.01: "The species are independent or distinct because [2]." *Id.* The MPEP requires that the Examiner "in bracket 2, explain why the inventions are independent or distinct." *Id.* Here, the Examiner's omission of this central sentence emphatically shows that he has failed to provide any such reasoning, and thus, has failed to meet his burden to justify election/restriction.

2. No Serious Burden Exists Because The Claims Have Been Searched And Examined Together Multiple Times.

Likewise, the Examiner has failed to provide any reasons as to why non-restriction imposes a serious burden. Nowhere in any of the Examiner's responses does he provide "the reasons why there would be a serious burden on the examiner if restriction is not required." *See* MPEP § 808. As discussed above, this election/restriction has come deep into the prosecution of the case, years after the subject matter of the claims was first presented, and well after the first Office action of August 30, 2005. Because the requirement for an election is untimely and follows several office actions on the merits, there is no basis for requiring withdrawal of any claims.

Accordingly, the undersigned hereby petitions that claims 1-8, 10-12, and 23-26 be reinstated and examined on the merits.

Although no fees are believed to be due, should there be any fees in conjunction with this petition, the Commissioner is hereby authorized to charge Kenyon & Kenyon LLP's deposit account no. 11-0600.

Respectfully submitted,

Date: April 17, 2007

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Claims

1. (Withdrawn) A method for removal of a selected portion of a therapeutic coating from a coated generally tubular medical device, comprising the steps of:

determining an amount of therapeutic coating on the medical device, wherein the medical device has a first end and has a lattice structure formed from a plurality of coated struts;

positioning the medical device on a holder, wherein the holder includes a retaining bar;

engaging the lattice structure of struts at the first end of the medical device with the retaining bar to maintain the medical device at a predetermined position relative to the holder;

identifying a location of at least one strut of the engaged medical device relative to a coating removal laser;

rotating the medical device relative to the coating removal laser; and

ablating the selected portion of the coating from the rotating medical device with the laser;

wherein the selected portion of the coating to be removed is a portion of the coating sufficient to reduce the amount of coating on the medical device to a target amount of coating.

2. (Withdrawn) The selective coating removal method of claim 1, wherein

the laser is controlled by a laser controller to distribute light energy over the selected portion, and

an amount of light energy distributed by the laser is sufficient to ablate the selected portion of the coating from the medical device.

3. (Withdrawn) The selective coating removal method of claim 2, wherein

the rotation of the medical device relative to the laser is controlled by a motion controller, and

the laser controller cooperates with the motion controller to control the laser to distribute light energy on the selected portion of the coating.

4. (Withdrawn) The selective coating removal method of claim 3, wherein

the laser controller controls the laser in accordance with a predetermined pattern as the medical device is rotated relative to the laser.

5. (Withdrawn) The selective coating removal method of claim 4, wherein the selected portion comprises a plurality of coating sections on the medical device.

6. (Withdrawn) The selective coating removal method of claim 5, wherein the selected portion comprises at least one circular coating section.

7. (Withdrawn) The selective coating removal method of claim 4, wherein the medical device is a stent.

8. (Withdrawn) A method for removal of a selected portion of a therapeutic coating from a coated stent, comprising the steps of:

providing a stent coated with a therapeutic agent, wherein the stent includes a plurality of coated stent struts;

providing a coating removal laser system, wherein the laser system comprises a laser and a laser controller to distribute light energy over a selected portion of a therapeutic coating of a coated stent;

providing a pattern recognition system;

identifying stent strut position relative to the laser with the pattern recognition system;

positioning at least one stent strut relative to the laser based on output from the pattern recognition system;

rotating the stent relative to the laser; and

ablating the selected portion of the coating from the rotating stent with the laser.

9. (Canceled).

10. (Withdrawn) The selective coating removal method of claim 1, wherein

the target amount of coating is a target weight of coating, and

the step of determining the amount of therapeutic coating on the medical device comprises subtracting a weight of the medical device from the weight of the coated medical device.

11. (Withdrawn) The selective coating removal method of claim 10, wherein the selected portion is at least one circular coating section.

12. (Withdrawn) The selective coating removal method of claim 11, wherein the medical device is a stent.

13. (Previously Presented) A selective coating removal apparatus for removal of a selected portion of a coating from a coated medical device, comprising:

a pattern recognition system;

a medical device rotator; and

a laser,

wherein

the pattern recognition system identifies the positioning of at least one strut of a medical device relative to the laser, determines whether the strut is in a desired position relative to the laser, and provides output to correct positioning of the strut relative to the laser, and

the laser ablates the selected portion of the coating from the medical device as the medical device is rotated by the rotator based on output from the pattern recognition system.

14. (Previously Presented) The selective coating removal apparatus of claim 13, further comprising:

a laser controller, wherein

the laser controller causes the laser to distribute light energy over the selected portion, and

an amount of light energy distributed by the laser is sufficient to ablate the selected portion of the coating from the medical device.

15. (Original) The selective coating removal apparatus of claim 14, further comprising:

a motion controller, wherein

the motion controller controls the rotation of the medical device relative to the laser, and

the laser controller cooperates with the motion controller to control the laser to distribute light energy on the selected portion of the coating.

16. (Original) The selective coating removal apparatus of claim 15, wherein the selected portion comprises a plurality of coating sections on the medical device.

17. (Original) The selective coating removal method of claim 16, wherein the selected portion comprises at least one circular coating section.

18. (Original) The selective coating removal apparatus of claim 15, wherein the medical device is a stent.

19. (Original) The selective coating removal apparatus of claim 15, wherein the selected portion of the coating to be removed is a portion of the coating sufficient to reduce the amount of coating on the medical device to a target amount of coating.

20. (Original) The selective coating removal apparatus of claim 19, wherein

the target amount of coating is a target weight of coating.

21. (Original) The selective coating removal method of claim 20, wherein the selected portion is at least one circular coating section.

22. (Original) The selective coating removal method of claim 21, wherein the medical device is a stent.

23. (Withdrawn) The selective coating removal method of claim 8, wherein

the rotation of the stent relative to the laser is controlled by a motion controller, and

the laser controller cooperates with the motion controller to control the laser to distribute light energy on the selected portion of the coating.

24. (Withdrawn) The selective coating removal method of claim 23, wherein the step of positioning at least one stent strut relative to the laser based on output from the pattern recognition system comprises correcting at least one stent strut position relative to the laser to improve ablation accuracy.

25. (Withdrawn) The selective coating removal method of claim 24, wherein the step of correcting at least one stent strut position relative to the laser comprises providing output to the laser controller to alter the distribution of light energy.

26. (Withdrawn) The selective coating removal method of claim 24, wherein the step of correcting at least one stent strut position relative to the laser comprises providing output to the motion controller to alter the rotation of the stent.